

United States Patent and Trademark Office

CNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 twww.usplo.gov

APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. 09/806,324 03/29/2001 Outi Vaarala 227-139 6790 EXAMINER 23117 7590 10/03/2003 NIXON & VANDERHYE, PC WONG, LESLIE A 1100 N GLEBE ROAD ART UNIT PAPER NUMBER 8TH FLOOR ARLINGTON, VA 22201-4714 1761

DATE MAILED: 10/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary Comparison of the cover sheet with the correspondence address Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM 1761	
Leslie Wong 1761 The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply	
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply	
Period for Reply	
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM	
THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status	
1) Responsive to communication(s) filed on <u>01 August 2003</u> .	
2a) ☐ This action is FINAL . 2b) ☑ This action is non-final.	
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. Disposition of Claims	
4)⊠ Claim(s) <u>13-34</u> is/are pending in the application.	
4a) Of the above claim(s) is/are withdrawn from consideration.	
5) Claim(s) is/are allowed.	
6)⊠ Claim(s) <u>13-34</u> is/are rejected.	
7) Claim(s) is/are objected to.	
8) Claim(s) are subject to restriction and/or election requirement. Application Papers	
9) The specification is objected to by the Examiner.	
10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.	
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).	
11)☐ The proposed drawing correction filed on is: a)☐ approved b)☐ disapproved by the Examiner.	
If approved, corrected drawings are required in reply to this Office action.	
12)☐ The oath or declaration is objected to by the Examiner.	
Priority under 35 U.S.C. §§ 119 and 120	
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).	
a) ☐ All b) ☐ Some * c) ☐ None of:	
1. Certified copies of the priority documents have been received.	
2. Certified copies of the priority documents have been received in Application No	
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 	
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application	n).
a) \square The translation of the foreign language provisional application has been received. 15) \square Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.	
Attachment(s)	
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s)	

Application/Control Number: 09/806,324

Art Unit: 1761

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 1, 2003 has been entered.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant does not clearly teach what steps are encompassed by "consisting essentially of."

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Page 2

Application/Control Number: 09/806,324 Page 3

Art Unit: 1761

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 13-34 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Vaarala et al (WO 98/48640).

Vaarala et al teach a process for removing bovine insulin from a protein material using a resin treatment combined with a filtration treatment as is claimed (see entire document). It is notoriously well-known that the resin (Amberlite manufactured by Rohm & Haas) utilized in Example 1 (page 8) is a styrene based adsorption resin.

Vaarala et al also disclose the reduction of the bovine insulin content of the protein (see page 7, lines 4 to page 8, line 30).

The claims appear to differ as to the recitation of specific pore size.

The pore size is seen as no more than inherent and/or obvious to that of Vaarala et al because the same resins are used.

It is noted that in view of the specification the use of "consisting essentially of" does not exclude the additional steps of Vaarala et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie Wong whose telephone number is 703-308-1979. The examiner can normally be reached on Tuesday-Friday.

Application/Control Number: 09/806,324

Art Unit: 1761

Page 4

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton Cano can be reached on 703-308-3959. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

Leslie Wong

Primary Examiner

Art Unit 1761

LAW

September 30, 2003